EXHIBIT “A”

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration

20

MAY 31 1979

Mr. Glenn P. Witte
International Association of
Ice Cream Manufacturers
910 Seventeenth Street, N.W.
Washington, D.C. 20006

Dear Mr. Witte:

This is in reply to your letter of May 11, 1979 concerning the labeling of ice cream containing naturally derived non-vanilla bean flavoring compounds to enhance, simulate and/or intensify flavor derived from vanilla bean.

The federal standard for ice cream 21 CFR 135.110 , has, since its promulgation in the early 1960's, provided for a system for designating characterizing flavors in ice cream which has come to be referred to as the "3 category flavor labeling". The syster recognizes three distinct types of ice cream, based on the use of natural and various combinations of natural and artificial flavors that characterize this food. The designation of a characterizing flavor for category I ice cream is based on the premise that only natural flavor derived from the product whose flavor is simulated may be used. The flavor designation for category II ice cream is on the basis that the product contains both natural and artificial flavor, but the natural flavor predominates, whereas in category III the artificial flavor predominates.

The definition and standard of identity as it pertains to the designation of flavors in the identity statement for ice cream was established long before the development of the general flavor regulations published under 21 CFR 101.22. Consequently, the labeling requirements for the declaration of flavors in the name of ice cream are specifically provided for by the standard. The general flavor regulations are not applicable to this standardized food.

While the requirements for flavor designation for category I ice cream are not all inclusive as written, the historical and current interpretation I believe is that the flavor agent for vanilla ice cream (a category I product) is limited to vanilla bean and/or flavor derived from vanilla beans.

It is our understanding that there are available in the market place, natural flavoring compounds that resemble, simulate and/or enhance vanilla flavor but are not derived from vanilla bean. These flavor compounds would not comply with the intent of the flavor provisions of Category I ice cream. However, they would qualify for category II labeling (vanilla flavored ice cream) provided that the flavor derived from vanilla beans predominates.

Sincerely yours,

Taylor M. Quinn
Associate Director
for Compliance
Bureau of Foods

EXHIBIT “B”

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

October 30, 1979

Mr. Daniel R. Thompson
Bonner, Thompson, O'Connell & Gaynes
900 Seventeenth Street, N.W.
Washington, D.C. 20006

Dear Mr. Thompson:

During our conference with you and Mr. Anthony Filandro, Vice President of Virginia Dare Extract Company, Inc., of Brooklyn, New York, on October 19, 1979 you raised a question concerning category II vanilla flavor in ice cream. You requested that we reply to your question in writing.

The ice cream standard under 21 CFR 135.110(e)(5)(i) states that an artificial flavor simulating the characterizing flavor shall be deemed to predominate in the case of vanilla beans or vanilla extract used in combination with vanillin, if the amount of vanillin used is greater than one ounce per unit of vanilla constituent as that term is defined in §169.3(c). Consequently, an ice cream manufacturer could not call his product "vanilla flavored ice cream" (Category II) if the flavor consisted of one ounce of vanillin per unit of vanilla constituent and any flavor from a non-vanilla bean source (which simulates, resembles, or reinforces the vanilla flavor) is added to the product. The non-vanilla flavor is deemed to simulate vanilla if the addition of the non-vanilla flavor results in a reduction in the amount of vanilla bean derived flavor that would otherwise be used in a vanilla flavored ice cream. Ice cream made from such a product would come under category III and have to be labeled as "artificial vanilla".

We hope this adequately answers the question you raised at our meeting.

Sincerely yours,

R. E. Newberry
Assistant to the Director
Division of Regulatory Guidance
Bureau of Foods

EXHIBIT “C”

(10)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

April 10, 1979

Mr. David B. Daugherty, President
Zink & Triest Company, Inc.
P.O. Box 321
Montgomeryville, Pa. 18938

Dear Mr. Daugherty:

This is in reply to your letter of 3/16/79 concerning the use of a flavor blend (other natural flavors) in category I ice cream.

The definition and standard of identity for ice cream (21 CFR 135.110) as it pertains to the designation of flavors in the identity statement for this food was established long before the development of the general flavor regulations published under 21 CFR 101.22. Consequently, the labeling requirements for the declaration of flavors in the name of ice cream are specifically provided for by the standard and is separate and apart from the general flavor regulations. Therefore, the standard for ice cream does not provide for the label designation of "With other flavors" (WONF).

A product identified as "Vanilla Ice Cream" is subject to the category I ice cream requirements and, therefore, must contain only the characterizing flavor derived from vanilla beans.

We hope this information is helpful.

Sincerely yours,

J. L. Summers

J. L. Summers
Assistant to the Director
Division of Regulatory Guidance
Bureau of Foods

EXHIBIT “D”

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Ice cream / Labeling - / Vanilla Flavoring

FEB -9 1983

Daniel R. Thompson, Attorney at Law
Bonner, Thompson, O'Connell, Gaynes & Middlekauff
900 Seventeenth Street, N.W.
Washington, D.C. 20006

Stephen A. Weitzman, Attorney at Law
Weitzman & Rogal
1320 Nineteenth Street, N.W.
Washington, D.C. 20036

Re: Labeling of Ice Cream Products Flavored with Vanilla Docket No. 80A-0209

Dear Sirs:

On May 16, 1980, the Flavor and Extract Manufacturers' Association (FEMA) filed a request for an advisory opinion regarding the labeling of ice cream products flavored with vanilla. FEMA presented a letter from a Bureau of Foods employee (the Newberry letter) and requested that the agency confer advisory opinion status on the letter's interpretation of the labeling requirements in the ice cream regulation (21 CFR 135.110). I signed an advisory opinion granting this request on February 12, 1981.

The ice cream regulation establishes a three-tiered system of labeling that is based on the amount of the natural characterizing flavor a product contains, and on whether, if the product contains both a natural characterizing flavor and an artificial flavor that simulates it, the natural characterizing flavor predominates. Under this system, natural vanilla flavor predominates, and ice cream can be labeled as "vanilla flavored," when the product contains one ounce of vanillin per unit of vanilla constituent. The advisory opinion sets forth FDA's view that when any flavor from a non-vanilla bean source that simulates vanilla is added to such a product, the natural flavor no longer predominates, and the product can no longer be labeled "vanilla flavored."

On February 23, 1981, David Michael & Co. (the objector) wrote to Secretary Schweiker and objected to this advisory opinion. On February 27, 1981, the agency stayed the opinion

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to consider the objection and to provide the objector with an opportunity to submit additional material.

I have now fully considered the issues raised by the advisory opinion and by the objection. I have carefully reviewed the extensive memoranda submitted by both the objector and FEMA, the attachments to these memoranda, and the written comments of the International Association of Ice Cream Manufacturers (IAICM). I have also met with representatives of the objector, IAICM, and FEMA.

As a result of my deliberations, for the reasons discussed below, I have decided to reaffirm the February 12, 1981 advisory opinion.

I. The Advisory Opinion Is An Interpretative Rule And Therefore Not Subject to Section 701(e) of the Food, Drug, And Cosmetic Act or to the Administrative Procedure Act

The objector contends that the advisory opinion effectively amends 21 CFR 135.110(e)(2)(ii) to prohibit the use of non-characterizing natural ingredients in "vanilla flavored" ice cream. Objector's April 6, 1981 submission, p. 35. The objector argues that the opinion thus was improperly issued because a standard of identity established under section 401 of the Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 341, can only be amended after compliance with section 701(e) of that statute, 21 U.S.C. 371(e).

The objector is incorrect for two reasons. First, as will be discussed in more detail below, the advisory opinion deals only with the effect on ice cream labeling of the use of flavoring ingredients that simulate the characterizing flavor. It has no bearing on the labeling of ice cream that contains flavors that do not simulate the characterizing flavor.

Second, and more importantly, under the test established in Gibson Wine Co. v. Snyder, 194 F.2d 329 (D.C. Cir. 1952), the advisory opinion is an interpretative rule. In Gibson Wine Co., supra, 194 F.2d at 331, the court stated:

> Generally speaking, it seems to be established that "regulations," "substantive rules" or "legislative rules" are those which create law, usually implementary to an existing law; whereas interpretative rules are statements as to what

the administrative officer thinks the statute or regulation means.

See also Cabais v. Egger, 690 F.2d 234, 238 (D.C. Cir. 1982). The February 12, 1981 advisory opinion presents the agency's view on how 21 CFR 135.110(e)(5)(i) requires a manufacturer to label a product that contains flavor consisting of one ounce of vanillin per unit of vanilla constitutent plus any amount of a flavor from a non-vanilla source that simulates vanilla. It does not make any change in 21 CFR 135.110(e)(5)(i).

In the preamble to FDA's proposed procedural regulations (40 FR 40682 (September 3, 1975)), the agency anticipated the situation presented here and specifically stated that whether the labeling of a product is consistent with the agency's regulations would be an appropriate subject for an advisory opinion. 40 FR 40695. Thus, the February 21, 1981 advisory opinion is an interpretative rule and is not subject to the provisions of 21 U.S.C. 371(e). (As an interpretative rule, the advisory opinion is also exempt from the provisions of the Administrative Procedure Act (APA). 5 U.S.C. 553(b)(B).)

The cases cited by the objector in its April 16, 1981 submission (pp. 29-34) are not to the contrary. Both Guardian Federal Savings & Loan v. Federal Savings & Loan Insurance Corp., 589 F.2d 658, 644 (D.C. Cir. 1978) and Chamber of Commerce of United States v. OSHA, 636 F.2d 464, 469 (D.C. Cir. 1980) utilize the test enunciated in Gibson Wine Co. v. Snyder, supra. Noel v. Chapman, 508 F.2d 1023 (2d Cir.), cert. denied 425 U.S. 824 (1975) and Parco v. Norris, 426 F.Supp. 976 (E.D. Pa. 1977) are not relevant. They relate to the distinction between general statements of policy and substantive rules and not to the distinction between interpretative and substantive rules. Finally, even if an agency action has substantial impact, it is still not subject to notice and comment rulemaking if, like the February 12, 1981 advisory opinion, it is otherwise expressly exempt under the APA. Cabais v. Egger, supra, 690 F.2d at 237.

Therefore, the February 12, 1981 opinion is not a substantive regulation and can properly be issued as an advisory opinion by FDA.

II. The Advisory Opinion Was Issued In Accordance With Appropriate Procedures

The objector has charged that even if the February 12, 1981 advisory opinion is an advisory opinion, it was issued in contravention of FDA's procedures on advisory opinions, the President's moratorium on regulations, and Executive Order 12291. Again, I find that I do not agree with the objector.

Section 10.85(a)(1) of FDA's regulations (21 CFR 10.85(a)(1)) enunciates the agency's policy of granting a request for an advisory opinion whenever feasible. In 1981, the agency found that it could issue an advisory opinion in response to FEMA's request. I find no basis upon which to conclude that this decision was inconsistent with 21 CFR 10.85.

Because the request for the advisory opinion seeks the agency's interpretation of an FDA regulation, the request presents a policy issue of broad application and not one applicable only to a particular product. Because FDA has long experience in administering the ice cream standard of identity, even though this matter is complex (see page 41 of the objector's April 6, 1981 submission), the agency had adequate information upon which to issue an informed advisory opinion in 1981. In addition, now that the agency has had the benefit of the comments of the objector, FEMA, and IAICM, there can be no question about the adequacy of the information underlying my decision to reinstate the advisory opinion. Finally, because there apparently is some confusion about the agency's interpretation of 21 CFR 135.110, it is in the public interest to issue this advisory opinion. Therefore, I find no basis in 21 CFR 10.85 for not reinstating the February 12, 1981 advisory opinion.

However, I agree with the objector that FEMA's request for an advisory opinion was not adequate under 21 CFR 10.85(b). A person who requests an advisory opinion from FDA has an obligation to provide a full statement of all facts and legal points relevant to the request. The requestor is not free, as FEMA did, to make assumptions about what information is or is not known to the agency. In addition, FEMA inaccurately described the Newberry letter in its request. The request states that the Newberry letter "...answers the question: What is the legal name of an ice cream product, the flavor of which 'consisted of one ounce of vanillin per unit of vanilla constituent and <u>any</u> flavor from a non-vanilla bean source....'" "Request for an Advisory

Opinion," dated May 16, 1980, from John G. Adams, past President of FEMA, p. 1. In fact, the Newberry letter was qualified and dealt only with those flavors from non-vanilla bean sources that "simulate, resemble, or reinforce" the vanilla flavor. FEMA's inaccurate description of the Newberry letter undoubtedly contributed to the confusion surrounding this proceeding.

In many cases, FDA would consider denying, under 21 CFR 10.85(a)(2)(i), a request like that submitted by FEMA because it presents insufficient information. The agency has committed itself to granting an advisory opinion when feasible (21 CFR 10.85(a)(1)); however, and in the circumstances presented here, for the reasons I have discussed, it is feasible to respond to FEMA's request.

The advisory opinion did not violate the President's moratorium or Executive Order 12291. Both of these directives applied only to regulations required to be promulgated by informal notice and comment rulemaking under the APA. As I explained previously, this advisory opinion is not the subject of notice and comment rulemaking. In fact, on February 10, 1981, Secretary Schweiker issued a memorandum to officials in the Department of Health and Human Services in which he stated that the President's directive does not apply to policy-setting actions outside the scope of the APA's informal rulemaking process. Among the examples he gave were interpretative rulings. As stated above, FDA's advisory opinions are interpretative rulings.

The objector also contends that FDA should have complied with the Regulatory Flexibility Act (RFA) in issuing the advisory opinion. By its terms, the RFA applies only to rules issued by notice and comment rulemaking, and, thus, this statute too does not apply to the advisory opinion.

III. The Advisory Opinion Is Correct And Is Consistent With Longstanding FDA Policy

After carefully considering all the information submitted on the appropriateness of the February 12, 1981 advisory opinion, I have concluded that that opinion is correct, and that it is consistent with the prior statements made by FDA. Therefore, I am reinstating this advisory opinion. However, before explaining the basis on which I reached these conclusions, I will address a preliminary matter that was debated in the comments on the advisory opinion. My determination on this preliminary matter establishes the foundation on which my other conclusions rest.

A. The Relationship Between §§135.110 and 101.22

The objection and the other comments FDA received on the advisory opinion contained a significant amount of discussion on the relationship between the ice cream regulation (21 CFR 135.110) and the general flavoring regulations (21 CFR 101.22). For example, the objector accused the agency of selectively borrowing from the general flavoring regulations in reaching its advisory opinion. See, e.g., Objector's April 3, 1981 submission, p. 41. After carefully considering this issue, I agree with the statement made by Taylor Quinn, Associate Director for Compliance of the Bureau of Foods, in his letter of May 31, 1979, to Glenn P. Witte of IAICM: "The general flavor regulations are not applicable to this standardized food [ice cream]."

The regulatory scheme under the general flavor declaration requirements of 21 CFR 101.22 is significantly different from the three-category labeling scheme in the ice cream regulation for declaring the characterizing flavor in ice cream. For example, under the general flavor regulations, if a food contains any artificial flavor that simulates, resembles, or reinforces the characterizing flavor, the food must be labeled "artificially flavored." 21 CFR 101.22(i)(2). In contrast, under the ice cream regulation, if the food contains both a natural characterizing flavor and an artifical flavor simulating it, the food need not be labeled as artifical unless the artificial flavor predominates (although when the natural flavor predominates, the presence of the artifical flavor must be indicated on the label). 21 CFR 135.110(e)(2)(ii). At the time FDA adopted the general flavor regulations, the agency considered revising the ice cream regulation to make it consistent with the general flavoring regulations. 38 FR 33284, 33287 (December 3, 1973). See also 39 FR 27144, 27145 (July 25, 1975). However, the agency ultimately decided to retain the three-category labeling scheme in the ice cream regulation. 42 FR 19127, 19131 (April 12, 1977). Because of the differences between the two regulations, the general flavoring regulations have no relevance to this matter.

However, the fact that the general flavoring regulations themselves are not relevant does not mean that all of the information contained in preambles to Federal Register notices on those regulations is also irrelevant. Not only is a preamble to a regulation an advisory opinion, 21 CFR 10.85(d)(1), but there is also a significant agency interest in being consistent among its regulations, at least in such matters as terminology. Therefore, a discussion in the pre-

amble to the general flavoring regulations about the meaning of a term that is used in the ice cream regulation as well as in the general flavoring regulations is applicable to both regulations.

One example of such a discussion is comment 17 to the December 3, 1973 final rule on the general flavor regulations. The paragraph explaining the subject of that comment states:

> 17. Questions have arisen as to how the characterizing flavor is to be determined, and as to how it will be determined whether added flavor "simulates" a characterizing natural flavor or otherwise characterizes the product.

Because the ice cream regulation also uses both "characterizing flavor" and "simulating," the discussion in comment 17 would obviously be relevant in interpreting the ice cream regulation as well as the general flavoring regulation.

On the other hand, because of the differences between the ice cream regulation and the general flavoring regulations, some agency discussions of one of these regulations will not be applicable to the other. For example, the Newberry letter concerns a product that contains a flavor consisting of one ounce of vanillin per unit of vanilla plus an additional amount of flavor from a non-vanilla bean source that simulates vanilla. Although such a product would be labeled as "artifically flavored" under both the general flavoring regulations and the ice cream regulations, the reasons for doing so would be completely different under §101.22 (the product contains artifical flavor, vanillin) than under §135.110 (the natural characterizing flavor does not predominate under the facts specified). Because the Newberry letter concerns only the application of the ice cream regulation, contrary to the claims of the objector (see Objector's submission of August 31, 1981, p. 8), it would not be relevant in interpreting 21 CFR 101.22.

B. The Advisory Opinion Correctly Interprets 21 CFR 135.110

Perhaps the best way to analyze the February 12, 1981 advisory opinion is to look at the portion of the Newberry letter that is quoted in the opinion on a sentence-by-sentence basis. There is no controversy about the first sentence, which merely restates the contents of 21 CFR 135.110(e)(5)(i), or about the last sentence, which simply follows from the two that precede it. The real concern is

over the middle two sentences. Thus, a closer analysis of these statements in the advisory opinion is necessary.

1. "Consequently, an ice cream manufacturer could not call his product 'vanilla flavored ice cream' (Category II) if the flavor consisted of one ounce of vanillin per unit of vanilla constituent and any flavor from a non-vanilla bean source (which simulated, resembles, or reinforces the vanilla flavor) is added to the product."

This sentence states that if any amount of flavor that simulates vanilla, the natural characterizing flavor, is added to the balance of vanilla and vanillin at which the vanilla is deemed to predominate, natural vanilla will no longer predominate. This statement is consistent with both 21 CFR 135.110 and the prior statements of the agency.

a. The use of the words "simulates, resembles, or reinforces" in this sentence, rather than the word "simulates" alone, is consistent with the agency's longstanding interpretation of the latter term. As explained above, it is appropriate to use the December 3, 1973 preamble in interpreting the ice cream regulation. In that preamble, in response to questions about how to determine "whether added flavor 'simulates' a characterizing natural flavor," the agency states that the test is not solely whether the flavor simulates or is chemically identical to the characterizing flavor, but also whether it resembles, reinforces, or extends it. 38 FR 33286. Thus, it was appropriate to incorporate "resembles" and "reinforces" into this sentence of the advisory opinion.

b. It is clear from the context in which the Newberry letter was written that the subject of the letter was a flavor that simulates the characterizing flavor. The Newberry letter was written after a meeting between Anthony Filandro of Virginia Dare Extract Co. and Daniel R. Thompson, counsel to FEMA, and Taylor Quinn, James Summers, and R. E. Newberry of FDA. The memorandum of this meeting indicates that Messers Filandro and Thompson inquired about the effect of "adding a natural flavor from a non-vanilla bean source which simulates, resembles, and reinforces the vanilla flavor." The Newberry letter, by its own terms, was intended to respond to this inquiry. Thus, the Newberry letter was not intended to set forth the effect of adding a non-characterizing flavor to a mixture of vanillin and vanilla constituent.

c. The Newberry letter is correct under 21 CFR 135.110(e). Because that section makes no provision for any natural flavors other than natural characterizing flavors, FDA must treat all natural flavors that simulate the characterizing flavor as artifical flavors when deciding what name should appear on the principal display panel. Thus, the addition of a flavor that simulates vanilla to ice cream that contains one ounce of vanillin per unit of vanilla constituent would mean that the balance at which the natural characterizing flavor -- vanilla -- predominates would no longer obtain. In such circumstances, the artificial flavor -- including natural flavors simulating vanilla -- will be deemed to predominate.

d. This sentence of the advisory opinion is consistent with prior statements made by the agency. On May 31, 1979, in response to a letter from Glenn P. Witte of the IAICM, Mr. Quinn wrote:

> It is our understanding that there are available in the market place, natural flavoring compounds that resemble, simulate and/or enhance vanilla flavor but are not derived from vanilla bean. These flavor compounds would not comply with the intent of the flavor provisons of Category I ice cream. However, they would qualify for category II labeling (vanilla flavored ice cream) provided that the flavor derived from vanilla beans predominates.

See also Letter of August 22, 1979, from Mr. Quinn to Kenneth B. Basa, National Food Ingredients Company, which contains a statement to the same effect.

Both the advisory opinion and the Quinn letter to Witte reflect the fact that FDA will treat natural flavor compounds that simulate vanilla but are not derived from vanilla beans as artificial flavors that simulate the natural characterizing flavor. The Quinn letter states that these natural flavor compounds can be used with natural vanilla flavors to make "vanilla flavored" ice cream, so long as the natural vanilla flavor predominates. The advisory opinion does not say that these compounds cannot be used to make such a product. What the advisory opinion does say is that if a natural flavor compound that simulates vanilla is added to vanilla flavored ice cream that is formulated at the point of predominance of the natural characterizing flavor (one ounce of vanillin per unit of vanilla constituent), the addition of this compound will mean that the natural characterizing

flavor no longer predominates. There is nothing in the Quinn letter to the contrary.

2. "The non-vanilla flavor is deemed to simulate vanilla if the addition of the non-vanilla flavor results in a reduction in the amount of vanilla bean derived flavor that would otherwise be used in a vanilla flavored ice cream."

a. The objector claims that the test embodied in this sentence establishes a minimum amount of natural vanilla flavored ice cream, and that the sentence consequently is inconsistent with 21 CFR 135.110. Objector's submission of August 31, 1981, p. 51. The objector misapprehends the meaning of this sentence. The sentence is not about how much vanilla must be in a product to call it "vanilla flavored" but about how to determine whether a flavor simulates the characterizing flavor. The agency first established this test in its response to comment 17 in the December 3, 1973 preamble. There FDA said that a flavor that extends the characterizing flavor, that is, makes it appear that more of the characterizing flavor is present than is actually the case, simulates the characterizing flavor. 38 FR 33286. Thus, a flavor that permits less of the characterizing flavor to be used than would otherwise be the case simulates that flavor.

The objector argues that comment 17 establishes taste as the only test for determining whether an added flavor simulates a characterizing natural flavor. Objector's submission of April 6, 1981, p. 54. In support of this contention, the objector cites the following language from comment 17:

> ...In determining whether added flavor does or does not simulate, resemble, or reinforce the characterizing flavor, the principal test will be to separate such added flavor from the product to determine whether it tastes like the characterizing natural flavor or approximates the flavor characteristics of any principal or key flavor note....

Id. In so arguing, however, the objector ignores the fact that the portion of comment 17 that he quotes speaks of the "principal test." Implicit in the use of these words is the fact that there are other criteria besides taste that are to be applied in deciding whether a flavor simulates the characterizing flavor. One of those tests is whether the flavor

extends the characterizing natural flavor. Thus, under comment 17, if an ice cream manufacturer added a small amount of a natural flavor not derived from the vanilla bean to his mix to permit the use of a smaller amount of vanilla-vanillin flavor, the natural flavor would simulate the characterizing flavor.

Therefore, the objector's claim that this sentence of the advisory opinion is inconsistent with 21 CFR 135.110 and with comment 17 in the December 3, 1973 preamble is without merit.

b. The objector contends that the test established in this sentence of the advisory opinion for determining whether a non-vanilla flavor simulates vanilla violates the principles established in United States v. 88 Cases, ... Birely's Orange Beverage, 187 F.2d 967 (3d Cir.), cert. denied 342 U.S. 861 (1951). Objector's February 23, 1981 submission, p. 8 and Objector's August 31, 1981 submission, p. 48. FDA finds this claim to be groundless.

The Birely's case turned on the question of whether there was any danger of confusing the product at issue with something else that is defined, familiar, and superior. 187 F.2d at 972. In Birely's, the court found that such a danger did not exist because there was no standard for diluted orange drinks like that made by the claimant, and because there was no danger that an ordinary consumer would confuse the claimant's product with undiluted orange juice. Id. at 973. Here, however, there is such a danger. Contrary to the claims of the objector (see Objector's submission of August 31, 1981, p. 51), FDA has established a standard for what can be called "vanilla flavored ice cream." The advisory opinion is intended to prevent consumer confusion by preventing the application of this name to products that do not meet the standard. Thus, the situation here is clearly distinguishable from that in the Birely's case.

For this reason, and because, as FEMA has pointed out, FEMA's submission of June 29, 1981, p. 18, this case involved application of section 401 of the FD&C Act, while Birely's involves application of section 402, and the two sections

have no relation to one another,*/ the principles enunciated in Birely's are not applicable to the immediate case

C. The Consumer Preference For Natural Flavors Is Irrelevant To This Matter.

The objector contends that the February 12, 1981 advisory opinion ignores the demonstrated consumer preference for natural products and for products that contain natural additives. Objector's April 6, 1981 Submission, p. 50. This contention may well be true, but it is irrelevant to a decision in this matter.

For ice cream, the name that appears on the principal display panel is determined by the factors set forth in 21 CFR 135.110(e). Under the labeling scheme established in that provision, whether a flavor is natural is significant only when that flavor is the characterizing flavor, in this case, vanilla. Any flavor, whether natural or not, that is used in ice cream to simulate the characterizing vanilla flavor is treated as an artificial flavor, unless it is derived from vanilla beans. If the objector wishes to change this scheme to reflect the claimed consumer interest in natural flavors, it is free to petition the agency to amend the regulation. For now, however, the advisory opinion must, as it does, reflect the regulation that is currently in effect.

IV. Conclusion

For the foregoing reasons, I find that the February 12, 1981 advisory opinion is consistent with 21 CFR 135.110 and with the prior statements made by FDA. Therefore, I am lifting the stay on the advisory opinion and reinstating this advisory opinion.

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*/ "...[S]ection [401]...has no relation to, no connection with, the adulteration provisions of the Act." Bruce's Juices v. United States, 194 F2d 935, 936 (5th Cir. 1952), citing United States v. 36 Drums of Pop'n Oil, 164 F.2d 150 (5th Cir. 1947).

On behalf of FDA, I would like to thank those who submitted comments and who met with me for their interest and contribution to the decisionmaking process in this matter.

Sincerely,

Joseph P. Hile

Joseph P. Hile
Associate Commissioner for
Regulatory Affairs

cc: John F. Speer, Jr., President
International Association of
Ice Cream Manufacturers
910 Seventeenth Street, N.W.
Washington, D.C. 20006

EXHIBIT “E”

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

AUG 22 1979

Mr. Kenneth B. Basa
National Food Ingredient Company
4830 S. Christiana Avenue
Chicago, Ill. 60632

Dear Mr. Basa:

This is in reply to your letter of July 31, 1979 concerning the use of vanilla-vanillin and natural non-vanilla derived flavorings in category II Vanilla Flavored Ice Cream.

We will respond to your questions in the order in which they appear in your letter.

1. Natural flavors not derived from vanilla beans may be used in combination with the standardized items included under 21 CFR 169 (vanilla-vanillin extract or vanilla-vanillin flavoring) for category II vanilla flavored ice cream provided that the flavoring contributed by or derived from the vanilla beans predominates.

2. The combination of vanilla-vanillin extract or vanilla-vanillin flavoring with natural flavors not derived from vanilla beans as provided above may be marketed in a single package. However, such a combination should in no way imply or suggest that this combination is one of the standardized flavors covered under 21 CFR 169.

3. The labeling for the above combination flavoring should identify what the combination is, e.g. "Vanilla-Vanillin Extract and____" (the blank to be filled with the names of the particular flavors used) or "Vanilla-Vanillin Extract with other natural flavors". The ingredient statement should declare the standardized flavoring by its specific common or usual name with a parenthetical listing of the optional ingredients required to be declared by the particular standard, and each ingredient of the natural non-vanilla flavoring should be declared by its specific common or usual names.

If we can be of further assistance, please let us know.

Sincerely yours,

Taylor M. Quinn
Associate Director
for Compliance
Bureau of Foods

EXHIBIT “F”

The Use of Vanilla in Ice Cream

Rules, Regulations and Interpretations - All Are Needed For A Thorough Understanding

J. Mark Black, Ph.D.
Spectra Flavor & Fragrance Research, LLC
7251 Paulsen Drive, Eden Prairie, MN 55346
mark.black@earthlink.net
952-294-0277

Much of the world loves vanilla ice cream. The flavor profile is intense enough to stand on its own, yet also is compatible with many other dessert foods. Indeed, it is the most popular flavor of ice cream in the world today, with more than a quarter of total ice cream market[1]. Most ice cream consumption is concentrated in North America, Europe and Australia with the United States leading all countries with about a quarter of the total consumption[2]. The market for frozen dairy confections in Asia is still relatively small but is rapidly growing, particularly the super-premium vanilla ice cream segment.

From a regulatory standpoint, vanilla is handled similarly to other flavors throughout most of the world. Country or region-specific flavor regulations apply to vanilla just like any other flavor. Thus, vanilla frozen confections manufactured for use outside the U.S. generally use conventional flavor nomenclature when naming their products. The U.S. flavor rules define vanilla flavor in a manner similar to the rest of the world (21 CFR 1:101.22, see Appendix A for full text) and these rules suffice for most products. The flavor rules also apply to vanilla used as a non-characterizing flavor in frozen dairy confections, such as in chocolate and strawberry ice creams. However, the flavor rules do not apply to vanilla used as a characterizing flavor in thus-named vanilla and vanilla-flavored ice creams.

There has been longstanding confusion within the U.S. food industry about how vanilla is defined for use in vanilla ice cream products. This is because the U.S. Code of Federal Regulations[3] (CFR) defines vanilla extract and frozen dairy confections as foods with standards of identity. Standards of identity are designed to assure consumers they are receiving products that contain the components they believe they are purchasing. This is conveyed through the product name on the principal display panel. Implicit in the term "Vanilla Ice Cream" is that the product contains the familiar ingredients of cow's milk, cream, sugar and vanilla extract. The CFR, through legal interpretations, has woven together the vanilla extract standards and the ice cream product standards so that they cannot be separated as the regulations stand today.

Because of its standard of identity, vanilla extract and related products are handled under a separate section of the CFR (21 CFR 1:169, see Appendix B for full text). This section clearly defines vanilla as the alcoholic extraction (35% v/v) of properly cured and dried pods of either *Vanilla planifolia* Andrews or *Vanilla tahitensis* Moore species. The ratio of dried pods (25% moisture) to 35% v/v ethanol is one pound/gallon. All folded vanilla products, extracts, concentrates, oleoresins and powders are based on this primary definition of vanilla extract. There are no requirements for standardization of vanillin content or flavor profile for vanilla extract.

The frozen confection standards are defined in a third section of the regulations (21 CFR 1:135, see Appendix C for full text). The CFR establishes a three-tiered nomenclature system for the principal display panel, specifically for vanilla and vanilla-flavored frozen dairy confections, based on the amount of natural flavor a product contains.

Category I: "Vanilla Ice Cream" contains no artificial flavor.

Category II: "Vanilla Flavored Ice Cream" contains a predominating, characterizing natural flavor and an artificial flavor simulating it.

Category III: "Artificially Flavored Vanilla Ice Cream" contains a predominating artificial flavor, used in combination with a natural flavor, or used alone.

The ice cream nomenclature rules, on their own, provide great latitude, thus confusion, in their interpretation. For example, the statement that Vanilla Ice Cream (Category I) contains no artificial flavor could be interpreted as the same as a natural flavor, as defined in the flavor rules (21 CFR 1:101), which can be compounded from natural flavor components obtained by different extraction and synthetic methods. For Vanilla Flavored Ice Cream (Category II), the CFR is not clear on what constitutes a "predominating" flavor; whether a flavor predominates by flavor intensity or by quantity. Because vanilla is a defined food, the CFR links the ice cream rules (21 CFR 1:135) to the vanilla rules (21 CFR 1:169) through the three-tiered nomenclature. However, the CFR does not call this out in the ice cream rules. Indeed, vanilla extract is not mentioned in any other part of the ice cream rules.

The industry sought clarification of these rules from the U.S. Food and Drug Administration (FDA). From 1979 to 1983, the FDA provided interpretations and ultimately an advisory opinion that clarified the rules around each category. However these have not been widely circulated, thus many ice cream manufacturers continue to be unsure about the legal status of their principal display panels.

The FDA clarified the use of natural flavor in Category I Vanilla Ice Cream in an interpretation issued to Mr. Glenn P. Witte of the International Association of Ice Cream Manufacturers[4]. Mr. Witte had requested clarification on the labeling of ice cream containing naturally derived non-vanilla bean flavoring compounds to enhance, simulate and/or intensify flavor derived from vanilla beans. This type of flavor is commonly called a vanilla WONF (with other natural flavors). Taylor Quinn (Associate Director for Compliance, Bureau of Foods, FDA) stated that "the labeling requirements for the declaration of flavors in the name of ice cream are specifically provided for by the standard. The general flavor regulations are not applicable to this standardized food." He summarized his opinion, saying "...the historical and current interpretation I believe is that the flavor agent for vanilla ice cream (a category I product) is limited to vanilla bean and/or flavor derived from vanilla beans." He further states "natural flavoring compounds that resemble, simulate and/or enhance vanilla flavor but are not derived from vanilla beans...would not comply with the intent of the flavor provisions of Category I ice cream." Therefore, the Quinn opinion clearly states that only vanilla from vanilla beans

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can be used for Category I Vanilla Ice Cream. Vanilla WONF cannot be used at any level to maintain Category I status.

The FDA clarified the Category II status in an opinion written to Mr. Daniel P. Thompson[5]. Mr. Thompson's question concerned the use of an artificial flavor in combination with vanilla and vanillin. R.E. Newberry (Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods) stated: "The ice cream standard under 21 CFR 135.110(e)(5)(I) states that an artificial flavor simulating the characterizing flavor shall be deemed to predominate in the case of vanilla beans or vanilla extract used in combination with vanillin, if the amount of vanillin used is greater than one ounce per unit of vanilla constituent as that term is defined in 169.3(c). Consequently, an ice cream manufacturer could not call his product 'vanilla flavored ice cream' (Category II) if the flavor consisted of one ounce of vanillin per unit of vanilla constituent and any flavor from a non-vanilla bean source (which simulates, resembles, or reinforces the vanilla flavor) is added to the product. *The non-vanilla flavor is deemed to simulate vanilla if the addition of the non-vanilla flavor results in a reduction in the amount of vanilla bean derived flavor that would otherwise be used in a vanilla flavored ice cream. Ice cream made from such a product would come under category III and have to be labeled as 'artificial vanilla'.*"

Newberry's logic can be extended also to Category I vanilla ice cream. His statement, that any flavor is characterizing that allows reduction of the amount of vanilla bean derived flavor in finished product, means that "non-characterizing" natural flavors cannot be added to Category I vanilla ice cream if their addition results in a reduction of vanilla extract. The product would be classified as Category II Vanilla Flavored Ice Cream. Newberry also links the vanilla extract rules (21 CFR 169.3) to the ice cream standards (21 CFR 135.110) when he discusses the use of vanillin to boost vanilla intensity for Category II and Category III products.

In 1980, the Flavor and Extract Manufacturers Association requested an advisory opinion from the FDA regarding the labeling of ice cream products flavored with vanilla. The FDA issued that opinion in 1981, which affirmed the conclusions of Quinn and Newberry. This advisory opinion was challenged and the conclusions were, yet again, reaffirmed in 1983[6].

The FDA has been clear and consistent in its interpretations of the use of vanilla in vanilla and vanilla-flavored frozen dairy confections. Only vanilla, derived from vanilla beans, may be used in Category I ice cream. No other flavors, that allow a reduction of vanilla in finished product, may be used for Category I vanilla ice cream. The FDA has been equally clear on its position with respect to Category II vanilla flavored ice cream. The FDA used the same logic that a flavor is characterizing if it allows a reduction in the total amount of natural vanilla added. Newberry used the example of one ounce of added vanillin per gallon of single-fold extract as qualifying for Category II vanilla flavored ice cream. Any further vanillin addition beyond the allowed one ounce, or the addition of any other flavor that results in a reduction in the amount of natural vanilla used would shift a product from Category II to Category III "Artificially Flavored". However, the flavorist has some latitude in flavor formulation for Category II products. Reducing the amount of vanillin added to vanilla extract in relation to the other added flavor compounds may provide flavor enhancement of natural extract while still meeting the FDA interpretation.

The vanilla rules are not a critical issue when vanilla bean prices are low and vanilla is readily available. The rules take on much greater importance when vanilla supply becomes short, prices skyrocket and quality is poor. The industry response to the recent vanilla crises has pointed out that the U.S. CFR regulations continue to confuse flavor vendors and ice cream manufacturers. However, when the regulations, interpretations and the advisory opinion are taken in context, there is a clear roadmap that can be used for formulation of vanilla frozen confections. The vanilla bean will live to fight another day.

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Appendix A

[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2004]
From the U.S. Government Printing Office via GPO Access
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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 101_FOOD LABELING--Table of Contents
Subpart B_Specific Food Labeling Requirements

Sec. 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.

(a)(1) The term artificial flavor or artificial flavoring means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. Artificial flavor includes the substances listed in Sec. Sec. 172.515(b) and 182.60 of this chapter except where these are derived from natural sources.

(2) The term spice means any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in Sec. 182.10 and part 184 of this chapter, such as the following: Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamon, Celery seed, Chervil, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace, Marjoram, Mustard flour, Nutmeg, Oregano, Paprika, Parsley, Pepper, black; Pepper, white; Pepper, red; Rosemary, Saffron, Sage, Savory, Star aniseed, Tarragon, Thyme, Turmeric. Paprika, turmeric, and saffron or other spices which are also colors, shall be declared as "spice and coloring" unless declared by their common or usual name.

(3) The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in Sec. Sec. 182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in Sec. 172.510 of this chapter.

(4) The term artificial color or artificial coloring means any "color additive" as defined in Sec. 70.3(f) of this chapter.

(5) The term chemical preservative means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

(b) A food which is subject to the requirements of section 403(k) of the act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food or on its container or wrapper, or on any two or all three of these, as may be necessary to render such statement likely to be read by the ordinary person under customary conditions of purchase and use of such food. The specific artificial color used in a food shall be identified on the labeling when so required by regulation in part 74 of this chapter to assure safe conditions of use for the color additive.

(d) A food shall be exempt from compliance with the requirements of section 403(k) of the act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

(e) A food shall be exempt while held for sale from the requirements of section 403(k) of the act (requiring label statement of any artificial flavoring, artificial coloring, or chemical preservatives) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either

(1) the labeling of the bulk container plainly in view or

(2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403(k).

(f) A fruit or vegetable shall be exempt from compliance with the requirements of section 403(k) of the act with respect to a chemical preservative applied to the fruit or vegetable as a pesticide chemical prior to harvest.

(g) A flavor shall be labeled in the following way when shipped to a food manufacturer or processor (but not a consumer) for use in the manufacture of a fabricated food, unless it is a flavor for which a standard of identity has been promulgated, in which case it shall be labeled as provided in the standard:

(1) If the flavor consists of one ingredient, it shall be declared by its common or usual name.

(2) If the flavor consists of two or more ingredients, the label either may declare each ingredient by its common or usual name or may state "All flavor ingredients contained in this product are approved for use in a regulation of the Food and Drug Administration." Any flavor ingredient not contained in one of these regulations, and any nonflavor ingredient, shall be separately listed on the label.

(3) In cases where the flavor contains a solely natural flavor(s), the flavor shall be so labeled, e.g., "strawberry flavor", "banana flavor", or "natural strawberry flavor". In cases where the flavor contains both a natural flavor and an artificial flavor, the flavor shall be so labeled, e.g., "natural and artificial strawberry flavor". In cases where the flavor contains a solely artificial flavor(s), the flavor shall be so labeled, e.g., "artificial strawberry flavor".

(h) The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way:

(1) Spice, natural flavor, and artificial flavor may be declared as "spice", "natural flavor", or "artificial flavor", or any combination thereof, as the case may be.

(2) An incidental additive in a food, originating in a spice or flavor used in the manufacture of the food, need not be declared in the statement of ingredients if it meets the requirements of Sec. 101.100(a)(3).
(3) Substances obtained by cutting, grinding, drying, pulping, or similar processing of tissues derived from fruit, vegetable, meat, fish, or poultry, e.g., powdered or granulated onions, garlic powder, and celery powder, are commonly understood by consumers to be food rather than flavor and shall be declared by their common or usual name.
(4) Any salt (sodium chloride) used as an ingredient in food shall be declared by its common or usual name "salt."
(5) Any monosodium glutamate used as an ingredient in food shall be declared by its common or usual name "monosodium glutamate."
(6) Any pyroligneous acid or other artificial smoke flavors used as an ingredient in a food may be declared as artificial flavor or artificial smoke flavor. No representation may be made, either directly or implied, that a food flavored with pyroligneous acid or other artificial smoke flavor has been smoked or has a true smoked flavor, or that a seasoning sauce or similar product containing pyroligneous acid or other artificial smoke flavor and used to season or flavor other foods will result in a smoked product or one having a true smoked flavor.
(7) Because protein hydrolysates function in foods as both flavorings and flavor enhancers, no protein hydrolysate used in food for its effects on flavor may be declared simply as "flavor," "natural flavor," or "flavoring." The ingredient shall be declared by its specific common or usual name as provided in Sec. 102.22 of this chapter.
(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:
(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the name of the food, except that:
(i) If the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in "strawberry shortcake", and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word "natural" and shall be immediately followed by the word "flavored" in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "natural strawberry flavored shortcake," or "strawberry flavored shortcake".
(ii) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as "artificially flavored."
(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words "with other natural flavor" in letters not less than one-half the height of the letters used in the name of the characterizing flavor.
(2) If the food contains any artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name(s) of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food and the name of the characterizing flavor shall be accompanied by the word(s) "artificial" or "artificially flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "artificial vanilla", "artificially flavored strawberry", or "grape artificially flavored".
(3) Wherever the name of the characterizing flavor appears on the label (other than in the statement of ingredients) so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, without any intervening written, printed, or graphic matter, except:
(i) Where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor; and
(ii) If the finished product contains more than one flavor subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such food, e.g., "artificially flavored vanilla and strawberry".
(iii) If the finished product contains three or more distinguishable characterizing flavors, or a blend of flavors with no primary recognizable flavor, the flavor may be declared by an appropriately descriptive generic term in lieu of naming each flavor, e.g., "artificially flavored fruit punch".
(4) A flavor supplier shall certify, in writing, that any flavor he supplies which is designated as containing no artificial flavor does not, to the best of his knowledge and belief, contain any artificial flavor, and that he has added no artificial flavor to it.

The requirement for such certification may be satisfied by a guarantee under section 303(c)(2) of the act which contains such a specific statement. A flavor user shall be required to make such a written certification only where he adds to or combines another flavor with a flavor which has been certified by a flavor supplier as containing no artificial flavor, but otherwise such user may rely upon the supplier's certification and need make no separate certification. All such certifications shall be retained by the certifying party throughout the period in which the flavor is supplied and for a minimum of three years thereafter, and shall be subject to the following conditions:

(i) The certifying party shall make such certifications available upon request at all reasonable hours to any duly authorized office or employee of the Food and Drug Administration or any other employee acting on behalf of the Secretary of Health and Human Services. Such certifications are regarded by the Food and Drug Administration as reports to the government and as guarantees or other undertakings within the meaning of section 301(h) of the act and subject the certifying party to the penalties for making any false report to the government under 18 U.S.C. 1001 and any false guarantee or undertaking under section 303(a) of the act. The defenses provided under section 303(c)(2) of the act shall be applicable to the certifications provided for in this section.

(ii) Wherever possible, the Food and Drug Administration shall verify the accuracy of a reasonable number of certifications made pursuant to this section, constituting a representative sample of such certifications, and shall not request all such certifications.

(iii) Where no person authorized to provide such information is reasonably available at the time of inspection, the certifying party shall arrange to have such person and the relevant materials and records ready for verification as soon as practicable: Provided, That, whenever the Food and Drug Administration has reason to believe that the supplier or user may utilize this period to alter inventories or records, such additional time shall not be permitted. Where such additional time is provided, the Food and Drug Administration may require the certifying party to certify that relevant inventories have not been materially disturbed and relevant records have not been altered or concealed during such period.

(iv) The certifying party shall provide, to an officer or representative duly designated by the Secretary, such qualitative statement of the composition of the flavor or product covered by the certification as may be reasonably expected to enable the Secretary's representatives to determine which relevant raw and finished materials and flavor ingredient records are reasonably necessary to verify the certifications. The examination conducted by the Secretary's representative shall be limited to inspection and review of inventories and ingredient records for those certifications which are to be verified.

(v) Review of flavor ingredient records shall be limited to the qualitative formula and shall not include the quantitative formula. The person verifying the certifications may make only such notes as are necessary to enable him to verify such certification. Only such notes or such flavor ingredient records as are necessary to verify such certification or to show a potential or actual violation may be removed or transmitted from the certifying party's place of business: Provided, That, where such removal or transmittal is necessary for such purposes the relevant records and notes shall be retained as separate documents in Food and Drug Administration files, shall not be copied in other reports, and shall not be disclosed publicly other than in a judicial proceeding brought pursuant to the act or 18 U.S.C. 1001.

(j) A food to which a chemical preservative(s) is added shall, except when exempt pursuant to Sec. 101.100 bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, e.g., "preservative", "to retard spoilage", "a mold inhibitor", "to help protect flavor" or "to promote color retention".

(k) The label of a food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section, except that colorings added to butter, cheese, and ice cream, if declared, may be declared in the manner specified in paragraph (k)(3) of this section, and colorings added to foods subject to Sec. Sec. 105.62 and 105.65 of this chapter shall be declared in accordance with the requirements of those sections.

(1) A color additive or the lake of a color additive subject to certification under 721(c) of the act shall be declared by the name of the color additive listed in the applicable regulation in part 74 or part 82 of this chapter, except that it is not necessary to include the "FD&C" prefix or the term "No." in the declaration, but the term "Lake" shall be included in the declaration of the lake of the certified color additive (e.g., Blue 1 Lake). Manufacturers may parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name as specified in part 74 or part 82 of this chapter.

(2) Color additives not subject to certification may be declared as "Artificial Color," "Artificial Color Added," or "Color Added" (or by an equally informative term that makes clear that a color additive has been used in thefood). Alternatively, such color additives may be declared as "Colored with ------" or "------ color", the blank to be filled with the name of the color additive listed in the applicable regulation in part 73 of this chapter.

(3) When a coloring has been added to butter, cheese, or ice cream, it need not be declared in the ingredient list unless such declaration is required by a regulation in part 73 or part 74 of this chapter to ensure safe conditions of use for the color additive. Voluntary declaration of all colorings added to butter, cheese, and ice cream, however, is recommended.

[42 FR 14308, Mar. 15, 1977, as amended at 44 FR 3963, Jan. 19, 1979; 44 FR 37220, June 26, 1979; 54 FR 24891, June 12, 1989; 58 FR 2875, Jan. 6, 1993; 63 FR 14818, Mar. 27, 1998]

Appendix B

The author has not included Sections 169.115 to 169.150 because they are not pertinent to the vanilla discussion.

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 169_FOOD DRESSINGS AND FLAVORINGS
Subpart A_General Provisions

Sec. 169.3 Definitions.

Subpart B_Requirements for Specific Standardized Food Dressings and Flavorings

169.115 French dressing.
169.140 Mayonnaise.
169.150 Salad dressing.
169.175 Vanilla extract.
169.176 Concentrated vanilla extract.
169.177 Vanilla flavoring.
169.178 Concentrated vanilla flavoring.
169.179 Vanilla powder.
169.180 Vanilla-vanillin extract.
169.181 Vanilla-vanillin flavoring.
169.182 Vanilla-vanillin powder.

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

Source: 42 FR 14481, Mar. 15, 1977, unless otherwise noted.

Subpart A_General Provisions

Sec. 169.3 Definitions.

For the purposes of this part:
(a) The term vanilla beans means the properly cured and dried fruit pods of *Vanilla planifolia* Andrews and of *Vanilla tahitensis* Moore.
(b) The term unit weight of vanilla beans means, in the case of vanilla beans containing not more than 25 percent moisture, 13.35 ounces of such beans; and, in the case of vanilla beans containing more than 25 percent moisture, it means the weight of such beans equivalent in content of moisture-free vanilla-bean solids to 13.35 ounces of vanilla beans containing 25 percent moisture. (For example, one unit weight of vanilla beans containing 33.25 percent moisture amounts to 15 ounces.) The moisture content of vanilla beans is determined by the method prescribed in Official Methods of Analysis of the Association of "Official Analytical Chemists," 13th Ed. (1980), sections 7.004 and 7.005, which is incorporated by reference, except that the toluene used is blended with 20 percent by volume of benzene and the total distillation time is 4 hours. Copies of the material incorporated by reference may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. To prepare samples for analysis, the pods are chopped into pieces approximately \1/4\-inch in longest dimension, using care to avoid moisture change.
(c) The term unit of vanilla constituent means the total sapid and odorous principles extractable from one unit weight of vanilla beans, as defined in paragraph (b) of this section, by an aqueous alcohol solution in which the content of ethyl alcohol by volume amounts to not less than 35 percent.

[42 FR 14481, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

Subpart B_Requirements for Specific Standardized Food Dressings and Flavorings

Sec. 169.175 Vanilla extract.

(a) Vanilla extract is the solution in aqueous ethyl alcohol of the sapid and odorous principles extractable from vanilla beans. In vanilla extract the content of ethyl alcohol is not less than 35 percent by volume and the content of vanilla constituent, as defined in Sec. 169.3(c), is not less than one unit per gallon. The vanilla constituent may be extracted directly from vanilla beans or it may be added in the form of concentrated vanilla extract or concentrated vanilla flavoring
or vanilla flavoring concentrated to the semisolid form called vanilla oleo-resin. Vanilla extract may contain one or more of the following optional ingredients:
(1) Glycerin.
(2) Propylene glycol.
(3) Sugar (including invert sugar).
(4) Dextrose.
(5) Corn syrup (including dried corn syrup).
(b)(1) The specified name of the food is "Vanilla extract" or "Extract of vanilla".
(2) When the vanilla extract is made in whole or in part by dilution of vanilla oleoresin, concentrated vanilla extract, or concentrated vanilla flavoring, the label shall bear the statement

"Made from ------" or "Made in part from ------", the blank being filled in with the name or names "vanilla oleoresin", "concentrated vanilla extract", or "concentrated vanilla flavoring", as appropriate. If the article contains two or more units of vanilla constituent, the name of the food shall include the designation "---fold", the blank being filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article.
(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the labeling required by paragraph (b)(2) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.
(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

Sec. 169.176 Concentrated vanilla extract.

(a) Concentrated vanilla extract conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by Sec. 169.175, except that it is concentrated to remove part of the solvent, and each gallon contains two or more units of vanilla constituent as defined in Sec. 169.3(c). The content of ethyl alcohol is not less than 35 percent by volume.
(b) The specified name of the food is "Concentrated vanilla extract ---fold" or "---fold concentrated vanilla extract", the blank being filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article. (For example, "Concentrated vanilla extract 2-fold".)

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

Sec. 169.177 Vanilla flavoring.

(a) Vanilla flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by Sec. 169.175, except that its content of ethyl alcohol is less than 35 percent by volume.
(b) The specified name of the food is "Vanilla flavoring".

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

Sec. 169.178 Concentrated vanilla flavoring.

(a) Concentrated vanilla flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla flavoring by Sec. 169.177, except that it is concentrated to remove part of the solvent, and each gallon contains two or more units of vanilla constituent as defined in Sec. 169.3(c).
(b) The specified name of the food is "Concentrated vanilla flavoring ---fold" or "---fold concentrated vanilla flavoring", the blank being filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article. (For example, "Concentrated vanilla flavoring 3-fold".)

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

Sec. 169.179 Vanilla powder.

(a) Vanilla powder is a mixture of ground vanilla beans or vanilla oleoresin or both, with one or more of the following optional blending ingredients:
(1) Sugar.
(2) Dextrose.
(3) Lactose.
(4) Food starch (including food starch-modified as prescribed in Sec. 172.892 of this chapter).
(5) Dried corn syrup.
(6) Gum acacia.

Vanilla powder may contain one or any mixture of two or more of the anticaking ingredients specified in paragraph (b) of this section, but the total weight of any such ingredient or mixture is not more than 2 percent of the weight of the finished vanilla powder. Vanilla powder contains in each 8 pounds not less than one unit of vanilla constituent, as defined in Sec. 169.3(c).
(b) The anticaking ingredients referred to in paragraph (a) of this section are:
(1) Aluminum calcium silicate.
(2) Calcium silicate.
(3) Calcium stearate.
(4) Magnesium silicate.
(5) Tricalcium phosphate.
(c)(1) The specified name of the food is "Vanilla powder ---fold" or "---fold vanilla powder", except that if sugar is the optional blending ingredient used, the word "sugar" may replace the word "powder". The blank in the name is filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per 8 pounds of the article. However, if the strength of the article is less than 2-fold, the term "---fold" is omitted from the name.
(2) The label of vanilla powder shall bear the common names of any of the optional ingredients specified in paragraphs (a) and (b) of this section that are used, except that where the alternative name "Vanilla sugar" is used for designating the food it is not required that sugar be named as an optional ingredient.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the labeling required by paragraph (c)(2) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.
(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2887, Jan. 6, 1993]

Sec. 169.180 Vanilla-vanillin extract.

(a) Vanilla-vanillin extract conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by Sec. 169.175, except that for each unit of vanilla constituent, as defined in Sec. 169.3(c), contained therein, the article also contains not more than 1 ounce of added vanillin.
(b) The specified name of the food is "Vanilla-vanillin extract ---fold" or "---fold vanilla-vanillin extract", followed immediately by the statement "contains vanillin, an artificial flavor (or flavoring)". The blank in the name is filled in with the whole number (disregarding fractions) expressing the sum of the number of units of vanilla constituent plus the number of ounces of added vanillin per gallon of the article. However, if the strength of the article is less than 2-fold, the term "---fold" is omitted from the name.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2887, Jan. 6, 1993]

Sec. 169.181 Vanilla-vanillin flavoring.

(a) Vanilla-vanillin flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla-vanillin extract by Sec. 169.180, except that its content of ethyl alcohol is less than 35 percent by volume.
(b) The specified name of the food is "Vanilla-vanillin flavoring---fold" or "---fold vanilla-vanillin flavoring", followed immediately by the statement "contains vanillin, an artificial flavor (or flavoring)". The blank in the name is filled in with the whole number (disregarding fractions) expressing the sum of the number of units of vanilla constituent plus the number of ounces of added vanillin per gallon of the article. However, if the strength of the article is less than 2-fold, the term "---fold" is omitted from the name.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2887, Jan. 6, 1993]

Sec. 169.182 Vanilla-vanillin powder.

(a) Vanilla-vanillin powder conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla powder by Sec. 169.179, except that for each unit of vanilla constituent as defined in Sec. 169.3(c) contained therein, the article also contains not more than 1 ounce of added vanillin.
(b) The specified name of the food is "Vanilla-vanillin powder ---fold" or "---fold vanilla-vanillin powder", followed immediately by the statement "contains vanillin, an artificial flavor (or flavoring)". If sugar is the optional blending ingredient used, the word "sugar" may replace the word "powder" in the name. The blank in the name is filled in with the whole number (disregarding fractions) expressing the sum of the number of units of vanilla constituent plus the number of ounces of added vanillin per 8 pounds of the article. However, if the strength of the article is less than 2-fold the term "---fold" is omitted from the name.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2887, Jan. 6, 1993]

Appendix C

Author has not included Sections 135.110 (a) through (e) because they are not pertinent to the vanilla discussion.

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 135_FROZEN DESSERTS--Table of Contents

Subpart B_Requirements for Specific Standardized Frozen Desserts

Sec. 135.110 Ice cream and frozen custard.

(f) Nomenclature.
(1) The name of the food is "ice cream"; except that when the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this section, the name of

the food is "frozen custard" or "french ice cream" or "french custard ice cream".

(2)(i) If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the words "ice cream".

(ii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words "ice cream", followed by the word "flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "Vanilla flavored", or "Peach flavored", or "Vanilla flavored and Strawberry flavored".

(iii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates, or if artificial flavor is used alone the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor in letters not less than one-half the height of the letters used in the words "ice cream", receded by "artificial" or "artificially flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "artificial Vanilla", or "artificially flavored Strawberry" or "artificially flavored Vanilla and artificially flavored Strawberry".

(3)(i) If the food is subject to the requirements of paragraph (f)(2)(ii) of this section or if it contains any artificial flavor not simulating the characterizing flavor, the label shall also bear the words "artificial flavor added" or "artificial ------ flavor added", the blank being filled with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.

(ii) Wherever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over: Provided, however, That where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand, may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor: And provided further, That if the finished product contains more than one flavor of ice cream subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such ice cream, e.g., "Vanilla flavored, Chocolate, and Strawberry flavored, artificial flavors added".

(4) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial flavor, displayed with substantially equal prominence, e.g., "strawberry and artificial strawberry flavor".

(5) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(i) In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used [[Page 368]] is greater than 1 ounce per unit of vanilla constituent, as that term is defined in Sec. 169.3(c) of this chapter.

(ii) In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished ice cream, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than 2 percent in the case of citrus ice cream, 6 percent in the case of berry or cherry ice cream, and 10 percent in the case of ice cream prepared with other fruits.

(iii) In the case of nut meats used in combination with artificial nut flavor, if the quantity of nut meats used is such that, in relation to the finished ice cream the weight of the nut meats is less than 2 percent.

(iv) In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in paragraph (e)(5) (ii) or (iii) of this section. For example, if a combination ice cream contains less than 5 percent of bananas and less than 1 percent of almonds it would be "artificially flavored banana-almond ice cream". However, if it contains more than 5 percent of bananas and more than 1 percent of almonds it would be "banana-almond flavored ice cream".

(6) If two or more flavors of ice cream are distinctively combined in one package, e.g., "Neapolitan" ice cream, the applicable provisions of this paragraph shall govern each flavor of ice cream comprising the combination.

(7) Until September 14, 1998, when safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in the food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one-half the size of the type used in the term "ice cream" but in any case no smaller than one-sixteenth of an inch. If the

food purports to be or is represented for special dietary use, it shall bear labeling in accordance with the requirements of part 105 of this chapter.

(g) Label declaration. Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that the sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of all the terms "milkfat and nonfat milk" when one or any combination of two or more of the ingredients listed in Sec. 101.4(b)(3), (b)(4), (b)(8), and (b)(9) of this chapter are used or, alternatively, as permitted in Sec. 101.4 of this chapter. Under section 403(k) of the Federal Food, Drug, and Cosmetic Act, artificial color need not be declared in ice cream, except as required by Sec. 101.22(c) or (k) of this chapter. Voluntary declaration of all colors used in ice cream and frozen custard is recommended.

[43 FR 4598, Feb. 3, 1978, as amended at 45 FR 63838, Sept. 26, 1980; 46 FR 44433, Sept. 4, 1981; 47 FR 11826, Mar. 19, 1982; 49 FR 10096, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2896, Jan. 6, 1993; 59 FR 47079, Sept. 14, 1994; 63 FR 14035, Mar. 24, 1998; 63 FR 14818, Mar. 27, 1998]